

R E M A R K S

Claims 1-11 have been cancelled without prejudice and replaced with new claims 12-21. New claim 12 corresponds to original claim 11. New claim 13 corresponds to original claim 2. New claim 14 corresponds to original claim 3. New claim 15 corresponds to original claim 4. New claim 16 corresponds to original 6. New claim 17 corresponds to original claim 7. New claim 18 corresponds to original claim 8. New claim 19 corresponds to original claim 9. New claim 20 corresponds to original claim 10. New claim 21 corresponds to original claim 1.

The original claims have been rewritten in U.S. form and the use language has been eliminated.

The rejection of claims 1-10 under 35 USC 112, second paragraph, is thus deemed to be overcome, as well as the rejection of the claims under 35 USC 101.

The new claims have been amended to specify that the patient population is an infant or a child. This amendment is supported in the specification. For example, see the paragraph bridging pages 2-3 of the specification. Lastly, new claim 21 has been drafted to include a pharmaceutically acceptable carrier, which is supported in the specification in the paragraph bridging pages 4-5 of the specification.

Accordingly, the rejection of claim 11 is deemed to be overcome.

Lastly, a Terminal Disclaimer is submitted over U.S. Patent No. 6,432,961.

The rejection under the judicially created doctrine of obviousness-type double patenting is thus deemed to be overcome.

Lastly, claims 1-11 were rejected under 35 USC 102 as anticipated by Trieloff. This ground of rejection is respectfully traversed.

Trieloff, (1995) briefly describes the background of the ETAC study protocol, based on interviews with German scientists in the field of allergy. It contains a summary of hitherto available prevention measures, i.e. allergen avoidance (mites, pets) and the rationale behind the start of the ETAC study: a double-blind placebo-controlled trial of cetirizine in infants (12-24 months of age) at high risk of asthma development due to a family history of asthma/allergy and

the presence of atopic dermatitis but no evidence of asthma - i.e. an attempt of primary prevention of asthma. The asthma risk was estimated to be 50% in this group of children. This publication was based on an attempt to improve recruitment to the study and contained no results of the study. Consequently it is clearly not enabling, nor does it provide any reasonable expectation of effectiveness of the claimed methods.

In view of the foregoing, it is believed that each ground of rejection set forth in the Official Action has been overcome, and that the application is now in condition for allowance. Accordingly, such allowance is solicited.

Respectfully submitted,

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